



Bio-Rad
Laboratories

Diagnostics Group
9500 Jeronimo Road
Irvine, California 92618-2017
Telephone: (949) 598-1200

CERTIFICATE-OF-ANALYSIS

Product Name: Lyphocek Diabetes Control
Master Batch Number: 85860
Product Base: Whole Blood
Physical Form: Lyophilized
Date of Manufacture: 2022-10-31

Description	Material Number	Batch Number	Expiration Date
Bilevel	740	85860	2025-10-31
MiniPak	740X	85860	2025-10-31

Testing Results:

Each human donor unit used to manufacture this product was tested and found non-reactive at the donor level per current applicable FDA requirements using FDA-accepted methods including testing for HIV-1/HIV-2 antibody, HBsAg, HCV Antibody, HIV-1 and HCV by a nucleic acid test (NAT).

Water Activity:	Specification: <0.200 aw	Level 1 < 0.030 aw	Level 2 0.055 aw
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Homogeneity Claim:

"Testing has been conducted to verify sufficient homogeneity in accordance with established requirements."

ADDITIONAL TESTING:

This product has been manufactured under applicable guidelines/standards and meets all established Bio-Rad quality requirements.

Approved By:

Date:

U. Hagnau
(QC Supervisor/Manager)

11-18-2022

P. Game
(QA Supervisor/Manager)

11/21/22

